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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,210	03/17/2005	Stephen R. Smith	3323	9149

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EXAMINER	
GOUGH, TIFFANY MAUREEN	
ART UNIT	**PAPER NUMBER**
1657	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,210	SMITH ET AL.	
	Examiner	Art Unit	
	Tiffany M. Gough	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/2007 has been entered.

Claims 49-69 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unilever PLC (EP 0466244 A1, 1992) in view of Medipharm (EP 0955061.A1,1999), Ibrahim (Natural food antimicrobial system, 2000) and Nippon (JP 62145025, 1987).

Applicant claims an antimicrobial composition used as an agent to suppress the growth of enteric pathogens such as *Clostridium perfringens, Escherichia coli, Salmonella typhimurium and Salmonella mbandaka*, either in powdered or aqueous solution or water-soluble form comprising a cell wall lysing substance or salt such as lysozyme, dried egg powder or albumen and a sequestering agent such as an organic acid or a metal chelator which is administered to feedstock as a feed additive to prevent and treat gastrointestinal infections such as necrotic enteritis and diarrheal disease in livestock. Applicant claims the composition ratio of such composition being 2:5:3 by weight. Further applicant claims the use of dried egg powder in such composition is capable of suppressing microbes such as molds and viruses and also enzymes like proteases and lipases in livestock gut. Further, applicant claims cell wall lysing substance or salt, dried egg powder or albumen, a sequestering agent and a lantibiotic such as nisin, whose ratio in composition is 50:150:50:20.

Unilever PLC (EP 0466244 A1, 1992) disclose a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of *Listeria monocytogenes* and also other microorganisms such as lactic acid bacteria which is

used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products (see abstract). They disclose the effectiveness of using lysozyme in combination with citric acid or EDTA and other chelators or an antimycotic such as Pimaricine™ in foods to inhibit *Listeria monocytogenes*, bacteria and yeasts (see pg. 2 "Use of lysozyme" section). Unilever discloses a strong synergism existing between the action of lysozyme, nisin and citric acid (EDTA or salts thereof can be substituted for citric acid). These three ingredients used together effectively prevent the growth of many strains of bacteria and are much more effective when used in combination than when used alone (see pg. 3 "Brief summary of invention and detailed description" paragraphs). They also suggest that antimycotics such a Pimaricine™ , which suppress the growth of molds and yeasts, can be used in combination with such mixture and further suggest that at least one antibacterial compound must be present in the synergistic composition (pg. 4 lines 20-24). Thus Unilever's invention is a composition, which has improved antibacterial properties, comprising a mixture of at least one representative of each group (a) a cell wall lysing substance (b) an antibacterial compound and (c) and adjuvant such as an organic acid or sequestering agent and further claims the following ratio of such composition (a) 5-2000 mg : (b) 5 x 10^3 -5 x 10^6 IU : (c) 0.5-100 g.

Unilever differs from the claims in that their composition is not disclosed as containing egg powder or albumen and further to suppress the growth of enteric pathogens, specifically *Clostridium sp. , E.coli* and *Salmonella sp.* However, Medipharm (EP 0955061 A1,1999) discloses an oral product for the prevention and

therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus, coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp. , E.coli* and *Salmonella sp.* The oral compositions raw material is liquid eggs, which are freeze-dried resulting in a powder form product, from which antibodies are obtained. The product exists in a paste, water-soluble powder formula which may be mixed with water, and a powder formula (see pg. 3 "Principle of invention" section).

Further support of the why one would use egg or albumin in an antimicrobial composition is provided by Ibrahim (Natural food antimicrobial system, 2000). Ibrahim discloses that an avian egg is one of many natural antimicrobial systems available. Egg whites, also known as albumin, is the eggs second line of defense against bacteria after the shell and membranes. The proteins in egg whites are thought to prevent invasion of microorganisms into the yolk and most posses antimicrobial properties which hinder the growth and spread of microorganisms. Such antimicrobial properties include lysozyme, which hydrolyzes the peptidoglycan of bacterial cell walls, ovotransferrin, which chelates metal ions, vitamin binding proteins and proteinase inhibitors (see introduction). Even further support is Nippon (JP 62145025, 1987) disclosing an antiviral agent containing albumen as an active component for the suppression of viruses such as rotavirus (see abstract).

One of ordinary skill in the art would therefore have been motivated by Ibrahim's disclosure of the antimicrobial properties eggs possess and to apply this knowledge to the composition in Medipharms application used for the prevention and therapy of porcine gastroenteric infections, more specifically directed towards the rotavirus,

coronaviruses and enteropathogenic and enterotoxigenic bacterial strains of *Clostridium sp.* , *E.coli* and *Salmonella sp.* and to further apply these advantages to the composition disclosed by Unilever containing a mixture of the cell wall lysing substance lysozyme, antibacterial/lantibiotic nisin and the sequestering agent citric acid or another food-grade adjuvant, effectively preventing the growth of *Listeria monocytogenes* and also other microorganisms such as lactic acid bacteria which is used in connection with suppression of microorganisms in production, packaging and storage of food products, animal feeds, cosmetics and pharmaceutical products.

With respect to the composition ratios in claims 10,16 and 22, optimizing the ratio as disclosed by Unilever is practiced through routine scientific experimentation. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the

motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). See MPEP 2144.05

Thus the claimed invention as a whole is prima facie obvious over the prior art.

Response to Arguments

Applicant's arguments filed 8/15/2007 have been fully considered but they are not persuasive. Applicant argues that a prima facie case of obviousness has not been established since there is no teaching suggestion or motivation to combine the references. In response to applicant's arguments that there is no motivation or teaching/suggestion to combine the elements of the claimed invention, applicant is advised that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*,--USPQ2d--,slip op at 20,(Bd. Pat. App & Interf. June 25, 2007) (citing *KSR*,82 USPQ2d at 1396) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf) .

Applicant states that," it is clear that the Examiner recognizes that Unilever does not teach an antimicrobial composition for suppressing the growth of enteric pathogens in the gut of livestock-which feature applicant considers to be a novel and unobvious feature of the claimed antimicrobial composition of claim 49." While Unilever does not teach the use of albumen in an antimicrobial composition, Medipharm was relied upon to overcome the deficiencies of Unilever. Further, applicant argues that the prior art of record teaches antimicrobial compositions and their use ex vivo and that the compositions do not suggest using such compositions for veterinary purposes, i.e. to

suppress the growth of enteric pathogens in the gut of livestock. It is noted that the cited reference, Unilever, does not teach the composition to be used in the manner instantly claimed. However, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting. Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Applicant states that the references may provide justification or expectation of success for adding egg or albumen to a composition where the antimicrobial activity of the composition occurs *in vivo* (i.e. in the gut of livestock) and targets the growth of enteric pathogens, yet cannot be distorted to provide motivation for the addition for a composition targeting bacterial growth *ex vivo.* Applicant's argument is not understood as applicant clearly admits that there is sufficient justification and expectation of success for adding egg or albumen to a composition where the antimicrobial activity of the composition occurs *in vivo* (i.e. in the gut of livestock) and targets the growth of enteric pathogens.

Applicant further provides reasons as to why one skilled in the arty would not be brought to combine the references; that one of skill in the art would not assume that the compositions of the prior art would be effective in suppressing enteric pathogens in the

gut of livestock, that the bacteria are different and thrive in different environmental conditions, etc. Applicant further states that the compositions of the prior art would not have any effectiveness whatsoever against enteric pathogens in the gut of livestock. However, the art of record clearly teaches the claimed composition's components, which are effective in treating and preventing gastrointestinal infections caused by enteric pathogens such as those claimed, i.e. *Clostridium sp., Salmonella sp. E. Coli.* Further, the claimed components; EDTA, citric acid, nisin, lysozyme and albumen, of applicant's compositions are well known for their bacteriostatic/bactericidal effectiveness against both gram positive and gram-negative bacteria. Such pathogens are also well known in the art to be enteric pathogens of the gut. Thus one of skill in the art would expect success in administering a composition comprising components which are known in the art for their antibacterial properties and effectiveness against enteric pathogens. Applicant's arguments of use of the compostion has been considered but is not persuasive. Applicant is directed to MPEP 2111.02 and 2112

2111.02 Weight of Preamble

"[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). **"If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim."** Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable inter alia of use as abrasive grains

and a binder is not an abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); Pac-Tec Inc. v. Amerace Corp., 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also In re Stencel, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar, however the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework – the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE

The claim preamble must be read in the context of the entire claim. **The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim."** Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. **If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction.** Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); Kropa v. Robie, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim); STX LLC. v. Brine, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000) (holding that the preamble phrase "which provides improved playing and handling

characteristics" in a claim drawn to a head for a lacrosse stick was not a claim limitation). During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims,manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, e.g., In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.); In re Sinex, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962) (statement of intended use in an apparatus claim did not distinguish over the prior art apparatus). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) (anticipation rejection affirmed based on Board's factual finding that the reference dispenser (a spout disclosed as useful for purposes such as dispensing oil from an oil can) would be capable of dispensing popcorn in the manner set forth in appellant's claim 1 (a dispensing top for dispensing popcorn in a specified manner)) and cases cited therein. See also MPEP § 2112 - § 2112.02.

Conclusion

No claims are allowed.

This is an RCE of applicant's earlier Application No. 10528210. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tiffany Gough

/Ruth A Davis/
Primary Examiner, AU 1651